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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/035,831 | 12/28/2001 | William P. Van Antwerp | 047711-0273 | 1788 |
| 7590 01/26/2006 | | | | |
| Irvin C. Harrington, III FOLEY & LARDNER 35th Floor 2029 Century Park East Los Angeles, CA 90067-3021 | | | EXAMINER BOUCHELLE, LAURA A | |
| | | | ART UNIT 3763 | PAPER NUMBER |

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/035,831 | Applicant(s) VAN ANTWERP ET AL. | |
| | Examiner Laura A. Bouchelle | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/03/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) 28-67 and 70-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 68 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/26/02, 3/20/03, 1/14/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Claims 1-27, 68 and 69 in the reply filed on 11/03/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

2. Claims 9 and 12 are objected to because of the following informalities: Claims 9 and 12 are both self-dependent. Appropriate correction is required. For the purpose of the current examination, it is assumed that claim 9 depends from claim 1; and that claim 12 depends from claim 9.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 9, 11, 12, 13, 14, 15, 16, 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al (US 4994047). Walker discloses a multi-layer catheter comprising

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tubing comprising at least one layer, wherein one layer includes a hydrophilic material that reduces the diffusion of molecules through the tubing (See Abstract). Walker discloses that the catheter can have two or three layers (Col. 12, lines 53-60). The hydrophilic layer is essentially polyurethane (Col. 4, lines 67-68) and can be either the inner layer or the outer layer (Col. 3, lines 4-7).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Ash et al (US 6042561). Claims 2 and 69 differ from Walker in calling for the insulin formulation to be maintained in the tubing. Ash teaches an infusion device comprising a continuous insulin infusion pump wherein the insulin is maintained in the tubing since the delivery is continuous (Col. 1, line 63 – Col. 2, line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Walker to maintain the insulin formulation in the tube as taught by Ash to prevent occlusions or deposits from forming in the tubing.

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Ash et al as applied to claim 2 above, and further in view of Brange et al (US

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4472385). Claim 4 differs from the teachings above in calling for the insulin to be a high concentration formulation. Claim 5 calls for the formulation to be greater than about 100 U/ml. Brange teaches a stabilized insulin preparation comprising a high concentration formulation of insulin at a concentration of 40 to 1000 U/ml (Col. 3, lines 50-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the insulin formulation of Walker in view of Ash to be of a concentration greater than about 100 U/ml as taught by Brange to achieve the optimal concentration.

8. Claims 3, 17, 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Brange et al (US 4472385). Claim 3 differs from Walker in calling for the insulin formulation to be stabilized by being substantially free of deposits or occlusions comprising insulin and an excipient. Brange teaches a stabilized insulin preparation comprising highly purified insulin and an excipient to provide the maximum concentration and stability (Col. 3, lines 45-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include in the device of Walker the insulin formulation of Brange so that the insulin has maximum stability.

9. Claims 17 and 18 call for the small molecules to be charged or not charged and the charged molecules to include metal ions. Brange teaches that the molecules contain magnesium ions to stabilize the insulin (Col. 3, lines 21-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include in the device of Walker the metal ions of Brange to stabilize the insulin.

10. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Brange as applied to claim 17 above, and further in view of Nelson (US 5702372). Claims 19- 24 differ from the teachings above in calling for the stabilizing catheter to reduce the flow of carbon dioxide or phenols into the tubing. Nelson teaches a lined infusion catheter comprising a liner made of Teflon that is relatively nonporous to prevent contaminants such as carbon dioxide from diffusing into the lumen and denaturing the insulin (Col. 4, lines 9-15). Adjusting the porosity and thickness of the liner is inherently capable of reducing the diffusion of contaminants any amount. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Walker in view of Brange to reduce the diffusion of carbon dioxide or phenol into the lumen as taught by Nelson to prevent the insulin from denaturing.

11. Claims 6, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of LeVeen et al (US 4448195). Claims 6 and 7 differ from Walker et al in calling for a layer to comprise glass and glass fiber. LeVeen et al teaches a catheter having a glass fiber layer to reinforce the catheter (Col. 2, lines 49-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the layers of Walker to have a layer of glass fiber as taught by LeVeen to reinforce the catheter.

12. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Burnham (US 4764324). Claims 6 and 8 differ from Walker et al in calling for the

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layer to have braided metal. Burnham teaches a catheter having a braided metal layer to reinforce the catheter against pressure (Col. 2, lines 10-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the catheter of Walker to have a braided metal layer as taught by Burnham to reinforce the catheter against pressure.

13. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of LeVeen et al or Burnham as applied to claim 6 above, and further in view of Nelson. Nelson teaches a catheter having a layer of Teflon that prevents diffusion of contaminants into the lumen (Col. 4, lines 10-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the catheter above to have a layer of Teflon as taught by Nelson to prevent contaminants from diffusing into the lumen.

14. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Ekwuribe et al (US 6309633). Claims 26 and 27 differ from Walker in calling for the protein to be the insulin analogue Lispro. Ekwuribe teaches the use of the insulin analogue Lispro in the place of insulin because Lispro has a more precise action profile than human insulin (Col. 14, lines 7-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Walker to have Lispro as taught by Ekwuribe because Lispro has a more precise action profile than human insulin.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle
Examiner
Art Unit 3763

LAB


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